

Attorney's Docket: 2003DE413
Serial No.: 10/791,577
Art Unit: 1713
Response to Office Action of July 27, 2004

REMARKS/ARGUMENTS

The Office Action mailed July 27, 2004 has been carefully considered together with each of the references cited therein. The amendments and remarks presented herein are believed to be fully responsive to the Office Action. Accordingly, reconsideration of the present Application in view of the following remarks is respectfully requested.

Applicant has amended the Application to attend to housekeeping matters and to more clearly describe the invention. Applicant has amended the Abstract of the Disclosure to reduce the length and format of the abstract to less than 150 words and to place the abstract in a single paragraph. Therefore, the objection to the Abstract of the Disclosure, as amended, should be withdrawn. The reference to the trademark "Lamepon S in paragraphs [00013] and [00015] was amended to be capitalized and the generic terminology "potassium cocoyl hydrolyzed collagen" was provided. Therefore, the objection for the uncertainty created by the not having a relationship between a trademark and the product should be withdrawn in light of the above amendment. Claim 1 and claim 15 and all dependent claims were amended to recite that the polymeric composition of the invention is water soluble. In claim 1, the term "substantially composed of" was replaced with the term - -consisting essentially of- -. In claims 1 and 15, the reference to R₆ was amended to correctly recite a C₁-C₄-alkyl, and the duplicate reference to "COOMe" was removed. Claims 7 and 16 which were the subject of a restriction requirement were canceled and new claims 17 and 18 were introduced to properly refer to a "water soluble" capsule or film comprising the polymeric composition of the invention. Support for these amendments may be found in Applicant's Specification in paragraph [00010] and originally filed claims 1, and 7. Claim 15 was further amended to include the limitations of claims 8 and 10. It is not believed that any new matter was introduced by these amendments, and that no additional search is required by the office. Claims 1-6 and 9-15 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 1 and 15 to

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remove the duplicate recitation of "COOMe", replaced the term "substantially composed of" with the term - -consisting essentially of--, and replaced the term "C₁-C₄" with the term C₁-C₄-alkyl with reference to R₆. Claims 1-6, 9-10, and 15 were amended to recite that the expressed percentages of the components of the polymeric composition are based on total composition. Support for these amendments may be found in originally filed claims 1-6, 9-10, and 15, and Applicant's Specification at paragraphs [0006] and [0007]. Regarding the recitation of the term "average molecular weight", Applicant recognizes that there are many way to recite the molecular weight of a polymer. Typically, the molecular weight of polyvinyl alcohol (PVA) is reported as an "average molecular weight" and refers to a weight average determination. Thus, one skilled in the art would not consider the recited "average molecular weight" as being indefinite. Please see the attached PVA specification sheet available at www.erkol.com from Erkol S.A., a Spanish chemical producer of PVA. It is believed that no new matter has been introduced by these amendments and that no additional search is required by the office. Therefore the rejection of claims 1-6 and 9-15, as amended, under 35 U.S.C. § 112, second paragraph, as being Indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention should be withdrawn in view of the above remarks and amendments.

Claims 1-6 and 9-15 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious in view of Takizawa et al. (US 4,777,089) or Takizawa et al. (US 4,908,233). The rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious in view of Takizawa et al. (US 4,777,089) or Takizawa et al. (US 4,908,233) should be withdrawn for the reason that the Takizawa references, which are identical ('233 is a continuation of '089), disclose a method for producing a microcapsules by coating them with a first water soluble polymer selected from the group consisting of polyvinyl alcohol, sulfated cellulose, water soluble nylon, gelatin, and poly(meth)acrylic acid, whereby this first water soluble polymer undergoes a phase separation in the presence of an electrolyte and a second water soluble polymer which does not undergo phase separation. A study on

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the effect of the electrolyte showed that the microcapsule is coated with the first water soluble polymer (See Column 2, lines 46-66) which is the only polymer which undergoes phase separation. Examples of the second water soluble polymer which "undergoes substantially no phase separation with an electrolyte are disclosed in the paragraph bridging column 5, lines 52 and column 6, line 8. Although the '089 reference discloses that thicker walls can be obtained when more than one second soluble polymer, such as pectin is used in combination with other second soluble polymers such as furcellaran, guar gum, gum karaya, etc. (See Column 6, lines 2-6) the microcapsule wall is only disclosed to contain PVA, which is the only water soluble polymer which undergoes a phase change (See Column 6, lines 52-55).

Applicant's invention relates to a water soluble polymeric composition which comprises from 50 to 99.9 wt-% polyvinyl and from 0.1 to 50wt-% polysaccharide, where the weight percentages are based on the total weight of the polymeric composition. Applicant prepares the polymeric material in a homogeneous aqueous phase and does not require the phase separation of the polyvinyl alcohol phase in order to provide the polymeric material (See Applicant's Specification at paragraph [0009]). Applicant's polymeric material differs from the composition of the '089 reference wherein an electrolyte is required to cause a phase separation in the PVA component from a second water soluble polymer, and the microencapsulate is formed in the PVA layer. In the instant invention, a homogeneous aqueous phase comprising both the PVA and the polysaccharide is formed, and upon cooling this homogeneous phase forms the polymeric material. Thus, Applicant's polymeric material actually comprises both the PVA and the polysaccharide, whereas the polymeric material of the '089 reference is limited to the PVA component. Therefore, the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious in view of Takizawa et al. (US 4,777,089) or Takizawa et al. (US 4,908,233) should be withdrawn for the reason that the '089 or '233 references do not disclose all of the elements of Applicant's invention and in fact teach away from the Applicant's invention. The '089 and the '233 references do not disclose that any of the polysaccharide is contained in the polymeric material, and teach away from the instant invention by the introduction of

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the electrolyte which causes the phase separation thereby limiting the formation of the polymeric layer to the first water soluble polymer which is disclosed to be PVA. Furthermore, no one skilled in the art armed with the teachings of the '089 or '233 references alone would be able to obtain the Instant invention which is based on a homogeneous combination and provides no teaching or motivation to one skilled in the art to modify the '089 or '233 references to achieve Applicant's invention.

The rejection of claims 2-6 and 9-15 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious in view of Takizawa et al. (US 4,777,089) or Takizawa et al. (US 4,908,233) should be withdrawn for the reasons given in support of claim 1 from which they depend.

Claims 1-6 and 9-15 were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roreger et al. (US 5,456,745). Roreger et al. teach flexible, hydrophilic, water-insoluble gel films which are capable of swelling under absorption of water, however, they are no longer soluble in water, even if heated (See column 1, lines 38-40). Roreger et al. disclose that the insoluble gel film sheet consists of:

- (a) 0.5 to 30%-wt of at least one water-soluble polymer being anion-active at neutral pH
- (b) 0.5 to 50%-wt of at least one water-soluble polymer being cation-active at neutral pH comprising type A gelatin
- (c) 0.1 to 20%-wt of at least one moisturizer comprising glycerol and
- (d) 0.1 to 70%-wt of water
- (e) 0 to 75%-wt of water-soluble or water-dispersible auxiliaries
- (f) 0 to 50%-wt of active substance

Roreger et al. in Column 2, lines 32 to 55 list some 6 major classes of materials for component (A) which includes anionic vegetable polysaccharides and provide as an example. Roreger et al. disclose that component (b) can be, for example, type A gelatin, and component (e) can include as water-soluble or water-dispersible auxiliaries, e.g. softeners, thickeners, penetrations accelerators, tackifiers, preserving agents, disinfectants, pH-regulators, antioxidants, emulsion stabilizers, cross-linking agents, fillers and/or foam stabilizers. In a further expansion of

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thickeners as a sub-class, polyvinyl alcohol is disclosed. Thus, Roreger et al. is directed to a different gel film with significantly different properties (water-solubility) and discloses hundreds, if not thousands of combinations of components. Anticipation is a technical defense which must meet strict standards: "Unless all the same elements are found in exactly the same situation and united in the same way to perform the identical function" in a single prior art reference, "there is no anticipation". The Roreger film is an **insoluble gel film**, the **present invention discloses a water-soluble film** and presents data which shows that film prepared according to Applicant's process comprising PVA and pectin resulted in a water soluble film (See solubility of films produced in Examples 1-4 in water at 40 and 60°C shown in the table preceding paragraph [00018]). The films of Examples 1-4 either broke up or dissolved. The Roreger et al. films are insoluble which may be the result of the additional required component (b) which is 0.5 to 50 wt-% of at least one water-soluble polymer which is cation-active at neutral pH, and is not found in Applicant's water-soluble film. Furthermore, no one skilled in the art armed with the teachings of the Roreger et al. reference would be able to obtain the instant invention which is based on a homogeneous combination consisting essentially of PVA and the polysaccharide of formula in claim 1. There is no teaching or motivation to one skilled in the art to modify the Roreger et al. reference to achieve Applicant's invention for a water-soluble film. To modify the Roreger et al. reference to provide a water-soluble film would be counter to the stated purpose of the Roreger et al. reference. Therefore, the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roreger et al. (US 5,456,745) should be withdrawn for the reason that the the Roreger et al patent is directed to a water-insoluble gel film and Applicant's invention is directed to a water soluble film using a limited selection of the extensive list of compounds disclosed in the Roreger et al. reference. However, unless all the same elements are found in exactly the same situation and united in the same way to perform the identical function" in a single prior art reference, there is no anticipation. Furthermore, Roreger et al. teach away from the instant invention by providing an

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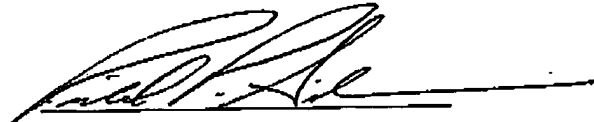
insoluble gel film. Therefore there can be no motivation or suggestion to one skilled in the art to modify the Roreger et al. reference to obtain Applicant's invention.

The rejection of claims 2-6 and 9-15 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious in view of Roreger et al. (US 5,456,745) should be withdrawn for the reasons given in support of claim 1 from which they depend.

It is respectfully submitted that, in view of the above remarks, the objections to the application and rejections under 35 U.S.C. §112, §102 and §103 should be withdrawn and that this application is in a condition for an allowance of all pending claims. Accordingly, favorable reconsideration and an allowance of all pending claims are courteously solicited.

An early and favorable action is courteously solicited.

Respectfully submitted,



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Attachments:

Erkol S.A, Specification Sheet for Polyvinyl alcohol

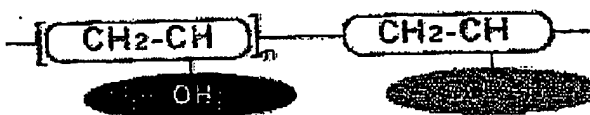
Polyvinyl Alcohol

[PVA ERKOL] [Characteristics] [Properties] [Packaging and Storage] [Other Information]

PVA Erkol

Erkol polyvinyl alcohol molecule

Erkol Polyvinyl Alcohol (PVA) is a synthetic resin produced by polymerisation of Vinyl Acetate (VAM) followed by hydrolysis of the Polyvinyl Acetate (PVAc) polymer. The degree of polymerisation determines the molecular weight and viscosity of Erkol in solution. The degree of hydrolysis (saponification) signifies the extent of conversion of the Polyvinyl Acetate to the Polyvinyl Alcohol.



Erkol Polyvinyl Alcohol is a Safe, Biodegradable, Water Soluble polymer with an enormous field of applications because of its unique set of properties.

n (Degree of Hydrolysis) = 68.2 - 99.8 Mol. %
MW (Weight Average Molecular Weight) = 10.000 - 190.000

PVA Erkol Characteristics

Erkol properties vary according to its Molecular Weight (MW) or polymer chain length and its Degree of Hydrolysis or Alcohol group (OH) content. The relation of principal Erkol properties with Molecular Weight and Degree of Hydrolysis is described in the attached table:

High Molecular Weight	Low Molecular Weight
<ul style="list-style-type: none"> - Solvent resistance - Tensile strength - Water resistance - Adhesive strength - Viscosity - Surface activity - Emulsifying / dispersing power 	<ul style="list-style-type: none"> - Solubility - Hygroscopicity - Flexibility
High Degree of Hydrolysis	Low Degree of Hydrolysis
<ul style="list-style-type: none"> - Solvent resistance - Tensile strength - Water resistance - Adhesion to hydrophilic surfaces - Viscosity 	<ul style="list-style-type: none"> - Solubility - Hygroscopicity - Flexibility - Bonding to hydrophobic surfaces - Surface activity - Emulsifying / dispersing power

General Properties

Appearance	PVA continuous: granular PVA discontinuous: powder
Refractive Index $n_D^{20^\circ\text{C}}$	1.52 - 1.55
Specific gravity	1.27 - 1.31
Specific heat (J/g K)	1.65 - 1.67
Thermal conductivity (W/m C)	~ 2
Mean coefficient of thermal expansion at 0-45°C (x 10 ⁻⁵ / °C)	7 - 10

<http://www.erkol.com/eng/Characteristics.htm>

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